the definition of healthcare entity and that blood centers are unique under the definitions of the act because their primary business may be considered to be that of a manufacturer and wholesaler. In fact, the vast majority of blood center commerce may be considered to be wholesale in nature.

Blood centers are also unique under the definitions in the act because they provide the manufacturers with the raw material from which blood derivatives are produced. A number of these blood centers have traditionally distributed these blood derivatives for years. These blood derivatives are a logical extension of the menu of blood products derived from whole blood. And, where there is distribution of blood derivatives by blood centers an important public service is provided. In times of shortage or product mix imbalances, blood centers who are engaged in distribution of blood derivatives have been able to assure a consistent supply to the same communities which made the starting material, the recovered plasma, available.

This is an effective and fair method of rationing which the PDMA would eliminate. In essence, plasma-derived products should be considered an extension of blood and blood components and excluded in the final rule because application of these products, just as with blood and blood products, into the PDMA could produce the same possible

shortages.

In summary, blood centers engaged in the wholesale distribution of blood derivatives should be permitted to continue because it is consistent with the intent of the PDMA. Blood centers have always acquired these products for the purpose of distribution among the hospitals they serve and there was never an intent to divert blood derivatives for any the reasons intended by the enactment of the PDMA.

Finally, the exclusion of blood centers from the distribution of blood derivatives through the PDMA has the potential to dislocate hospitals from a reliable supply of blood derivatives in periods of product shortage, which would seriously affect the supply to patients. The business purposes of blood centers engaged in the distribution of blood derivatives are consistent with the intent of the PDMA, and blood centers should, therefore, be exempt from the definition of healthcare entity as currently described in the PDMA.

I thank you for your time, and we would be happy to entertain questions.

MS. AXELRAD: Thank you very much. I wish we had chairs for you. You are welcome to sit at the table, or something. I am going to turn to my colleagues in CBER to begin this.

MS. JACOBS: The first question I would like to

ask is Diane Maloney, our Associate Director for Policy in CBER, in her introductory remarks said that one of the things that had been suggested to us was to define healthcare entities in a somewhat different way so that it would potentially exclude blood centers that had minimal activity. I know that Laura McDonald, you discussed that this was at the edge of the definition. I wonder if you would want to expand, and possibly Dr. Bianco might, on exactly what the healthcare services are that you provide and how they fit into a total healthcare scheme.

MS. MCDONALD: Well, Dr. Bianco could describe them further but, as he said, only about five percent of our business could be considered healthcare in that we provide services such as therapeutic phlebotomy or therapeutic apheresis of plasma as treatment for certain diseases. Our core business is to collect and process and test blood and blood component and derivative products.

MS. JACBOS: And that is what you meant by saying that you could be seen as a manufacturer and a wholesaler out of which the healthcare entity was allied to that role?

MS. MCDONALD: Well, I think our interpretation is that the only reason we are considered healthcare entity is those few services we provide, as opposed to a hospital or a clinic.

DR. BIANCO: Excuse me, Mary Elizabeth, that is

actually a very good question. FDA treats us as manufacturers. We have all the requirements of manufacturers -- Good Manufacturing Practices and everything to fulfill our establishment licenses. But, these medical services in general communities, small hospitals, do not have the resources to provide them. The bulk of our business is with healthy people -- our healthy donors that come to donate blood and help their communities. Some of those services are, for instance for a patient with hemochromatosis who needs to be bled every few weeks in order to reduce their iron; an individual that is in need of therapeutic apheresis; a person that needs a stem-cell collection. In general, many hospitals are not set up with the sophistication, the equipment or the expertise to provide these, so these are provided as community services by blood centers throughout the country in Red Cross centers, in America's Blood Centers, BCA. From the volume and from the financial point of view, I would guarantee that in no center it exceeds five percent.

MS. JACOBS: Okay. Let me ask one other question then, you have mentioned how you have handled shortage situations, and those have been brought to FDA's attention and are Blood Products Advisory Committee in great detail. But I think it would be helpful for the purposes of this decision-making forum for you possibly to discuss a bit in

terms of the impact of the IGIV community, etc. I thought it was interesting that actually the submission by Mr. Lamb has a reference to the alpha-1 foundation because one of the economists they have worked with has worked with that community. So, if you could just document something to quantify the shortages and how you have functioned in a way to ensure supply without hoarding.

MR. BIANCO: Well, I can give you a local perspective in New York, and this was mostly with hemophilia-related drugs, particularly Factor VIII. In shortages or certain types of products, or when certain types of products were, for instance, withdrawn from the market because the manufacturer, for instance, had regulatory issues, we worked together with the physicians in terms of optimizing the doses, reducing the prophylactic doses that are given to certain groups of patients so that they could have more product available for other patients, and they made an assessment of risk of those patients. Hemophilia patients are very well informed; they really know what is going on, and all that, and they really also have a sense of community so there is that desire to share, and when the physicians and we discuss with them that we will deliver smaller amounts of products for a period, a change to other products that they can tolerate and so we, together with the physicians, in this small environment can very

effectively manage the shortages, the product withdrawals, the recalls that may happy that on occasion would empty our shelves of certain type of product, as you very well know.

MR. LAMB: With regard to the IGIV shortage, the way the American Red Cross has helped to alleviate this issue, which is still an issue today, is that the American Red Cross, as I mentioned, processes over a million liters of plasma from its whole blood collections. We have established a contract manufacturing relationships with companies like Baxter and Swiss Red Cross. So, what we do is the plasma is separated from the whole blood. It is then rushed to the manufacturing or fractionation facility. That fractionation facility contracts or manufactures on behalf of the American Red Cross. They provide back, for example, polygam, which is an IGIV product that is manufactured by Baxter on behalf of the American Red Cross. They label it for the American Red Cross. As soon as it is manufactured, each batch must be approved by the FDA. We work closely with the FDA to make sure that they expeditiously approve the batches. It is moved to our warehouse and immediately distributed back out to hospitals and, essentially, over the past two or three years we have operated on virtually no inventory. As soon as it is received into our possession we distribute it back out, in some cases to other blood centers who then distribute it to their hospitals, or directly to

hospitals or to homecare companies or clinics.

So, if you introduce yet another entity between the American Red Cross another distribution, it is another pocket of inventories, another way to increase the price during the shortage. So, while we have not been able to totally mitigate the shortage, we have been able to work closely with hospitals and patient groups to minimize to the extent possible. We also work with the immune deficiency foundation on a safety net program where we have set aside a stock of product so that if physicians can't get product for primary immune deficiency they can access the American Red Cross product through the safety net program. So, we have worked both with the patient groups and with the hospitals and patients to get them product as quickly as possible. So, there is little inventory in the system and people can get product as they need it.

MS. STIFANO: I have a question. It has been brought to our attention that there is a movement for companies or a company to try and establish direct ship to customers. These are particularly hemophilia patients. Given that situation, what percent of the hemophilia patient population do you serve right now in the current distribution system versus what would happen if you didn't get this ability to provide service?

DR. BIANCO: I have to say I don't know. There

are approximately 20,000 hemophiliacs in the country. The two major centers serving them are Puget Sound and New York. We serve about 600 in New York City at New York Blood Center. But, I could not come up with exact figures. The major ways by which these patients are served, they are served through hemophilia treatment centers, many federally funded centers, through some homecare companies through which they can have health insurance, which are also smaller entities in terms of the purchasing power, and some hospitals. But, the majority of them are through these two mechanisms.

I believe, and that is a community approach, that when they are served by regional blood centers there is a better balance in how the resources are distributed throughout the community. But, in our system there are the other options and many patients are actually very happy following, for instance the homecare companies.

MR. LAMB: Basically, in the hemophilia market in the United States it is about 800 million units, and probably the way the American Red Cross and blood centers like the New York Blood Center which has organized a consortium in the New York area which has been very successful in distributing products to hemophilia patients, the Puget Sound blood center -- I would guess, although I am fairly knowledgeable about the market, would be about

twenty-five percent that is provided through the American Red Cross or community blood centers.

There has been a recent controversy. One particular pharmaceutical company, Bayer, established a Bayer direct program, which received a tremendous amount of discussion on this topic. I think the American Red Cross supports, you know, patient options and we provide products both to the New York consortium, for example, and the Puget Sound system and to other healthcare entities to ensure that patients can get the product through the mechanism that they want it. But, we are certainly aware of the situation and it is not one that we are in any way connected with.

DR. BIANCO: But I could say that we at least don't like the program.

[Laughter]

MS. AXELRAD: Thank you very much. We have one person who is in the audience who has indicated that they would like to make a few remarks. Mr. Shirley? Would you please identify yourself for the record, and your affiliation?

MR. SHIRLEY: Steve Shirley. I am president of R&S sales, Fountain Run, Kentucky. We are a member of NWDA. We employ about 55 employees.

I don't have anything written out word by word, but there were some topics that came up today that I thought

I might expand on a little bit. We have been in business since 1982. In 1982, in Kentucky, there was no wholesale license. I was a registered pharmacist. I worked retail for a year and a half when I started in the business. There was no wholesale license that I could obtain to do business with. We just bought product and resold it in the wholesale market.

In 1984 Kentucky adopted a wholesale license and we were one of the first wholesalers in Kentucky to obtain that license. When the Prescription Drug and Marketing Act came up in 1987, part of that provision was that it required states to have requirements for each wholesaler.

One of the topics that has been brought up today is why has it been better since the Prescription Drug Marketing Act than it was before. The primary reason is the requirements of wholesale licenses. Now, when my company buys from anybody or sells to anybody, there is a license that we have on record for the purchase or for the sale, be it a retail license for the pharmacies or a wholesale license for the wholesaler.

There has been a lot of discussion about the pedigree and the intent of Congress. I think it is pretty clear in the record that the intent of Congress was not to put small wholesalers, like ourselves and the 4,000 other ones out there, out of business. The intent of Congress was

to have safe products in the market which the licensing helped to improve. John Dingell is a co-sponsor of 4301, which basically says that, hey, the pedigree -- we need to put on each form that this was bought through an authorized distributor. If anybody who has a license lies on that, the same penalties apply to them as the pedigree.

There are three reasons that I have sort of heard you all talk about today of what makes the pedigree great. There is a safety issue, a tracing of the drug issue, and it might make recalls a little bit better. Now, you all might come up with another one here after I talk and I would be glad to give you my insight on that, the safety issue comes down to three: counterfeits, adulteration or misbranding. Okay, if somebody out there that has a wholesaler license, because you have to remember in the market today we only to business with licensed wholesalers and if they adulterate, misbrand or counterfeit, will they hesitate one second about counterfeiting a paper trail that they send to anybody? I don't believe they will. A criminal is a criminal. They adulterate and misbrand, and have no care for public safety. So, they are not going to hesitate to counterfeit the paper trail. If we have 4301, it is going to say that this was bought from or through an authorized distributor. I guarantee the authorized distributor is not going to be the counterfeiter, the misbrander or the adulterator. Someone

there did so they just lied on that form that they just sent to the end user.

So, John Dingell is a co-sponsor on that bill. So, Congress's intent was not to put us out of business. The system that we have lived under since 1987 has been that if we are not authorized and -- first of all I deplore the word authorized and unauthorized. All the wholesalers in the United States have the same licensing requirements. I am licensed just like the "big five" guys are. I have the same requirements but you all are sitting around and saying I am unauthorized. I am authorized to carry every pharmaceutical in the United States right now but a C-II. So, I prefer the terminology of authorized distributor, which, you all are allowing the manufacturers the term because they are the ones who say you are authorized or you are not. It is not any legal department here that is saying I am authorized or not; it is the manufacturers. So, the term should be authorized distributor versus licensed wholesaler; not unauthorized distributor because I am authorized for all of them.

So, we go back to the safety issue. The paper trail does not improve safety one bit because that guy is going to lie on it anyway. You have penalties for that under 4301 or under the current bill. What we have been doing before is saying we will give paper trails back to an

authorized distributor. Why does one more step improve safety?

The reason we have such a problem with it right now is the wholesalers that we buy from, the big ones, can't provide us that information. It is physically impossible for them to do it, and I will explain that a little bit later. That is the reason I am so disturbed about your new provision. We have worked under the proposed reg for twelve years and then, all of a sudden, we have changed and said, hey, it is not the authorized distributor no more; we have to go back to the manufacturer.

The second part on the paper trail is the tracing of drugs that was brought up. If there is a drug that, hey, we need to find out where this came from, in a period of thirty minutes, from a phone call, any agencies, be it FDA, DEA, state board of pharmacy that we are under too, can say, okay, who did you buy this from? There is an invoice of where it came from. It has the phone number on it. They can call. He can look it up and see where it came from.

So, you are applying regulations for something that really is not improving the tracing of the drug because I have records there of every place I ever bought the product from. I can throw every pedigree away and you can trace every drug I have. That has been in effect the whole time. So, the pedigree does not improve the traceability.

Now let's talk about recalls. How does a pedigree improve recalls? Recalls come from the top down. Manufacturers create recalls. Wholesalers receive those recalls. FDA, I believe, can issue recalls. They can go through wholesalers and it is sent to the customers. Where, in that scenario, did the pedigree come up? It wasn't going to the pharmacy looking at the pedigree, oh, we need to recall this and go back up the other way. If there is a problem with the product, we will go to the FDA or the manufacturer. If there is a problem, we do a recall. It goes down to the wholesalers and we send it out to our distributors. So, I do not understand how the pedigree improves safety, traceability or drug recalls.

Now, I said I would answer why it is hard for the full-line wholesalers to provide paper trails to us. Number one, under the law they are authorized distributors so they don't have to provide it in the first place. There has been discussion about saying, hey, let's make everybody provide it. I think I proved there were no advantages of why everybody should provide it.

Think of the logistics that have to happen and which we have to do at our place that the other guys are not doing now. You get a palette of any drug in that may have ten lot numbers in it. Under the law that we have right now, we have to record those ten lot numbers. When we sell

it to somebody we have to record which lot number we sold them. We have to record what date those lot numbers were sold. And, two days later I get in another palette and the full-line wholesaler gets in another palette that has the same lot numbers but they receive those on another date, so the way we do our logistics at our place, we have to store those ten lot numbers on ten different shelves. The full-line wholesalers have space problems like everybody else. They have a bin for a product. When they receive an order for a product, I have never seen a drugstore receive an invoice from a full-line wholesaler that has a lot number recorded on it. They are not pulling lot-specific items that I have seen to go to the drugstore level or to any other level.

So, basically, what we have been doing is when we receive the product -- as a matter of fact, I will add to that, about half the manufacturer invoices we receive do not have lot numbers on them.

MS. AXELRAD: Well, then how do you do a recall if you do not know what lot --

MR. SHIRLEY: You do a recall because when I receive a recall I will, first of all, go to my shelf and say, do I have that lot number? We look through every item to see if we have the lot number. The other wholesalers -- that is how recalls work. They go to the shelves to see if

they have that lot number. Then we send letters to all our customers. They do the exact same thing. It is not a tracking, in my opinion, of lot numbers; it is a tracking of say do you have that lot number? No, I don't. I am clear of the recall. I will send my letters out. Or, yes, I do. I will pull it off. I will return it and I will send it on down. That is the reason I am saying the recalls are top down, not bottom up.

MS. O'ROURKE: Wait, if you say if you get a recall notification, you are going to look at your stock --

MR. SHIRLEY: Right.

MS. O'ROURKE: But, presumably, you have some sort of computer system or you can check back for stock that has already been shipped because you still have to notify people.

MR. SHIRLEY: I can't. As far as I am concerned, I don't think the full-lie wholesalers can. You are welcome to ask NWDA that. They weren't able to attend. You know, I think that is a good question to ask them. In my opinion, I don't think they can because I do not believe the full-line wholesalers, the "big five" that you have heard about today that have ninety percent of the product, can tell you where a specific lot number was shipped.

As one of the wholesalers talked to you earlier, the people in receiving -- not only do we count the product

that comes in, every bottle has to be looked at to record the lot number -- everyone that comes in. Then it goes to separate shelves based on what those lot numbers are. Now, that receiving goes to our receiving in the computer department and this guy is recording every lot number on every shelf and then, when it is typed, the people have to pull that specific lot number off that specific shelf in compliance with the current regulations. The authorized distributors do not have to do that because they do not have to provide a paper trail. They physically, logistically can't provide that to us.

So, if you leave the current regulations the way you are, you are not deciding that we need to do it this way; you are deciding that all the small wholesalers need to be out of business.

You brought up the bar coding idea. Personally, my opinion, if the bar code had the lot number in there, I would love it because I would buy bar coding immediately and I could cut down, but as far as my limited amount of knowledge, I don't think it is in there now. I think it just identifies the product by the UPC number, which really doesn't serve a purpose. But if they got the lot number in there, I think it would save us time and money at our place if it was there.

MS. AXELRAD: Is that put on by the manufacturer?

MR. SHIRLEY: Yes. There are just some little numbers that I wrote down here. If a wholesaler does -- and I want to use the word produce -- produce an adulterated or counterfeit product, there are laws in place to penalize them. Plus, the way you guarantee somebody is not in this business is pull their wholesale license. In '87, when they made the law and started talking about pedigrees you have to remember all the states didn't have wholesale licenses. So, they uniformed the standards on all of it. Now all of them do. And, we don't do business with anybody that doesn't have a wholesale license.

It was brought up about a standard pedigree form, which sounds like a great idea. Everybody's computer system is different. Our computer system -- we put out all the information that is required by the PDMA. If you put out a standard form I have to reprogram my computer to make it look like your standard form. I would imagine every wholesaler would have to do that too to make it look like a standard form. The thing is, everybody puts that information on there a little different way.

The new regulations that you wrote are guaranteeing that there will be less competition in the market. I know that your all's primary concern is safety issues and not economic issues. But less competition, guys, guarantees eventually that there are going to be higher

prices.

I guess the one last thing that I will leave you with and I will let you ask me questions is I truly do not understand why you wish to give the manufacturers authority to say that I am authorized or I am not. I would love for FDA to tell me if I am authorized or not. Right now, I have every license that every authorized distributor has but the terminology here today is that I am authorized for some products, and I am authorized for quite a few, but I am not authorized for others.

An example of what would happen in my business if I didn't have the capability to transfer product, and I don't want to get into the big topic of flu vaccine because I can't talk about it much but there are two or three manufacturers of flu vaccine. If I have an account with Evans and Evans gets back-ordered and I can't get it anymore. If I have to order a Connaught product and then try to redistribute it, I have to have a computer system in place to do a paper trail because I am not authorized. The only reason I am not authorized is not because of licensing, it is because Connaught did not have me in their computer as authorized. What is fair about that?

I know you all have to write regs based on what Congress writes up, but there is nothing -- if I have the license of the big guys, give the a chance to compete with

the big guys. I know you all can't change the law. I am not saying that, but let's get down to the logic of it. Pedigrees, they sound real pretty but in the end they serve no purpose. The '87 bill that was written up, great bill. It got everybody on the same standard for wholesale licenses. I loved it. As a matter of fact, I loved it when Kentucky got a wholesale license in '84 because a lot of people didn't understand why Kentucky didn't have a wholesale license. But it got everybody on the same page.

The pedigree -- I don't know where they came up with it exactly but there were states that didn't have wholesale license at that time and I don't know if it had any influence on it. But, we can accomplish the purposes of safety without putting us out of business.

MS. AXELRAD: Thank you. I have one question. I am going to ask Mr. Young the same question in a minute. HR-4301 says that if you are not an authorized distributor you provide either the pedigree or a statement that the drug was first purchased from or through an authorized distributor. Now, how do you think that that would help?

MR. SHIRLEY: Basically, what that does is any law that you have is based on how severe the penalties are. The penalties for breaking PDMA -- it has some severe penalties in there. If you have a company -- on the safety issue, and I go back to adulterating, misbranding or labeling, for that

to have occurred, and then they put a paper trail that that came from or through an authorized distributor, they just lied. So, they are under the same penalties that the pedigree was under. Do you follow what I am saying?

MS. AXELRAD: Sort of, but the question is who would supply that in the first place? The only person who could supply that piece of paper in the first place, who would know where it came from would be somebody who bought the drug from an authorized distributor. Then, wouldn't that person have to pass that piece of paper on, along with the drug, so that if you are the seventh, you know, secondary wholesaler down the line who is handling this lot of the drugs, or whatever, how would you know that seven times ago it came through an authorized distributor?

MR. SHIRLEY: It goes about like the pedigree toes. Number one, you are telling me that I send the pedigree out to somebody now and they are trusting that I send a truthful pedigree. Right now, if I buy from one of the big wholesalers that is an authorized distributor and I put on there that this was bought from an authorized distributor, the people I am selling to are trusting me to tell them the truth. What is the difference in telling the truth that I bought this from an authorized distributor or telling the truth that I bought it with a name, address and phone number?

MS. AXELRAD: Well, I am just saying that the piece of paper would have to be created by a person who first bought it from an authorized distributor --

MR. SHIRLEY: Right.

MS. AXELRAD: -- it would then have to be passed on by everybody else.

MR. SHIRLEY: That is what we are doing with pedigrees right now.

MS. AXELRAD: Yes, well, I am trying to figure out why everybody thinks that this certification statement which is put in instead of the pedigree would be any less burdensome, given that it is a piece of paper that has to be passed along with the drug for every transaction.

MR. SHIRLEY: Okay. Number one, right now I have a pedigree that I have to pass along through every transaction. With the new form of 4301 I can put down that I bought it from an authorized distributor. I still have all my records here of where everything came from, but I didn't have to pay employees that the big guys didn't have to pay to put in all the information on lot numbers, pulling the exact lots. We still have the record there of where everything came from. Either way, you are sending paper down all the way down through, pedigree or the statement. It just makes it a lot easier on the smaller wholesalers to send the statement.

If I am licensed by the board of pharmacy -- and I am not supposed to ask you questions, if I am licensed, just like McKessen is, why should I have more paperwork than McKessen? I have the same license. I am inspected by the same inspector. I am under the same laws.

MR. RAY: Well, I think you have to kind of deal with the premise that Congress dealt with when they first passed the law. They thought, obviously, that there were enough problems out there that wouldn't be remedied just by wholesale licensing, otherwise, you know, what would be the need for the pedigree requirement?

MR. SHIRLEY: Well, to go back to the pedigree requirement, if a crook is a crook he is going to lie on the pedigree too.

MS. O'ROURKE: Mr. Shirley, would you say that 4301 -- you say that instead of having to pass along the pedigree, you would just have to include in your invoice or a separate piece of paper the statement that this drug originally was passed through an authorized distributor. Because you can only provide information on where you bought the drugs, and the authorized distributor might have been six suppliers back and you won't have those records, would it turn out to be essentially a good faith situation where you believe your supplier? When they say they got it from an authorized distributor you wouldn't be able to know but

it would be a good faith issue.

MR. SHIRLEY: I believe the current pedigree system is a good faith issue now, ma'am.

MS. O'ROURKE: Why?

MR. SHIRLEY: A guy sends me a piece of paper saying where he bought it from. How do I know for sure, with one hundred percent accuracy, that he got it there? Or, he writes he bought it from an authorized distributor. Both of them are good faith.

MS. O'ROURKE: Okay. So, then the relationships are more or less based on good faith rather than -- essentially earlier testimony stated that there were relationships, where you know your suppliers.

MR. SHIRLEY: They are based on good faith but they are also based on wholesale licenses. If somebody does not have a wholesale license they are not in this industry. There are regulations on wholesale licenses now. You know, pull their license. If somebody does something wrong I want them out of the industry.

MS. AXELRAD: It is up to the state to do that.

MR. SHIRLEY: I understand that but they have regulations.

MS. AXELRAD: But I am sure that, just like in many other areas, the states are not totally consistent in all fifty states in regulating this, and these people are

shipping across all fifty states.

MR. SHIRLEY: I don't know about the enforcement. I believe the PDMA, when it was written, set minimum standards for each state that they had to put the wholesalers under. I don't know about the enforcement of each state but I think there are minimum standards for every state.

MS. AXELRAD: Right, but if they don't enforce them it doesn't make any difference.

MR. SHIRLEY: Absolutely.

MS. AXELRAD: I am still trying to get at this HR-4301. Maybe if it passes we can call the form 4301. But, they do two things in here. One is that they broaden the definition of authorized distributor so that as long as you buy some drug from a company in a calendar year you are an authorized distributor. Then they say, and if you are not an authorized distributor, then you have to supply either the certification or the pedigree. What percentage of the problem would just opening up who is an authorized distributor -- all you have to do is buy from the manufacturer, you know, one sale in a calendar year and you become an authorized distributor -- wouldn't that solve the problem without having to get into this business of the certification?

MR. SHIRLEY: Basically -- let me think for a

second, here.

MS. AXELRAD: How many people buying things don't buy anything from a manufacturer during a calendar year?

MR. SHIRLEY: That only depends if the manufacturer with set you up with an account, ma'am, and that is not based on any criteria. I would welcome the committee to call any manufacturer and ask him what is your criteria for setting up a wholesaler? I have never heard of one. It is totally at their discretion.

As far as the authorized distributor issue, I don't understand the definition of authorized distributor. You know, according to the regs and the way we have been running for twelve years, if you made two transactions you were an authorized distributor. What was the need of changing it?

MS. AXELRAD: That is what I am trying to get at. They are changing both things in the law. Is there really a need to change both things.

MR. SHIRLEY: Basically, your suggestion regs changed saying that we have to have a contract with them.

MS. AXELRAD: Right.

MR. SHIRLEY: If you all didn't change your all's opinion, we needed that changed.

MS. AXELRAD: So, if we went back to two transactions in a 24-month period --

MR. SHIRLEY: That part doesn't need to be changed.

MS. AXELRAD: -- you wouldn't need to go back and change the law. All --

MR. SHIRLEY: Well, now, let me ask you this, why do you want me to keep paying more money to run my business than the big guys do? Do you want to keep penalizing the small wholesaler? It is a lot easier and financially beneficial to me to put it on the invoice that this was bought from an authorized distributor. Why not give the small guys a break instead of giving the big guys a break?

MS. AXELRAD: I was trying to get at that one --

MR. SHIRLEY: I understand the question, but, hey, all I want is a level -- you hear "playing level field" a lot in Washington and I will use it -- I want a level playing field so I get a chance to compete. Right now, I have been able to compete. I mean, we are located in rural Kentucky. We have a great work force and great people that we are working with, and we have been able to compete even though we have had disadvantages. 4301 is a great bill. When I am regulated by the same agency as the other guys, give me the same laws as the other guys. They don't have to do it; I shouldn't have to do it.

MR. RAY: I think her question, though, is do you really need both parts of that?

MR. SHIRLEY: Yes.

MR. RAY: Why?

MR. SHIRLEY: Okay, why do we need the pedigree? I have explained why the pedigree doesn't serve a purpose. You are really saying, hey, we really want this pedigree. With the pedigree you are taking somebody at their word. There are no safety issues through the pedigree. There are no tracing issues. There are no recall issues. And, you are sitting there, saying that, boy, I hope 4301 doesn't pass because I want them to keep doing that pedigree. The pedigree doesn't serve a purpose, guys. Let our people live.

MR. RAY: You need to convince Congress of that.

MR. SHIRLEY: Well, that is what we are hoping to do with 4301 but I am having a hard time convincing you, all, so far and I don't get to talk to Congress in person.

MR. RAY: Write your congressman.

MS. AXELRAD: I mean, you could just delete (e)(1)(a) if the statute. You could just delete the whole section. I am trying to figure out what do you get by keeping the section this way.

MR. SHIRLEY: You are talking about the authorized distributor part?

MS. AXELRAD: No, I am talking about the section that says each person who is engaged in the wholesale

distributor of a drug is subject to subsection (b), and who is not the manufacturer or an authorized distributor or record of such drug shall before each sale or distributor of such drug, including each distribution to an authorized distributor of record or to a retail pharmacy, write to the person who receives the drug a statement in such form -- yes, it is a pedigree requirement basically. But what we are doing is sort of altering the pedigree requirement in such a way that you are both broadening the definition of authorized distributor in another section and having the certification requirement. Why not just get rid of the provision? If almost anybody can be an authorized distributor, and even if you are not an authorized distributor all you need to do is provide the certification, what is the point of having the provision in the first place?

MR. SHIRLEY: I will make one argument for not getting rid of the total provision. You can put another nail in the guy's coffin that if he lies and he counterfeited, adulterated or misbranded a product he lied on the statement and you can get him under another law.

MS. AXELRAD: Yes, but who? The only person you can get is the first person who manufactured the statement if they didn't buy it from an authorized distributor.

MR. SHIRLEY: Isn't that the one you want?

MS. AXELRAD: Well, maybe --

MR. SHIRLEY: I mean, you don't want somebody --

MS. AXELRAD: -- you have to figure out who that was.

MR. SHIRLEY: Oh, you can figure out who it was. All the records, back up the chain. You give me a phone and I can call for thirty minutes and find out where everything came from.

MS. AXELRAD: Can we hire you to do that?

MR. SHIRLEY: Oh, yes.

[Laughter]

MS. O'ROURKE: I thought we just heard that no one would give that information because it is anti-competitive.

MR. SHIRLEY: There is one thing, guys, when a federal agency walks in we will give you any information you want. We don't like giving the information to our competitors or to retail drugstores because a very good instance is I buy from a major wholesaler. I sell to a retail drugstore. It is one of his accounts. He looks at the paper trail. He calls the major wholesaler and says why are you selling this guy in Kentucky cheaper than you are selling me? And, the guy has to explain that I bought 1,440 pieces as compared to one piece. It causes grief. That is one reason why I don't like the paper trail thing because you cause me grief in that if they got a lot of phone calls

they wouldn't like selling to me.

MR. MCCONAGHA: I just want to clarify your response to her question. I take it when you are talking about 4301, you like to some degree the definition of authorized distributor because it is watered down. So, it is better than it is under the reg that we propose --

MR. SHIRLEY: The new reg that you proposed. That is right.

MR. MCCONAGHA: Well, in the best of all worlds, you just get rid of the pedigree altogether and you can probably live with the certification -- that is really what the response is. I just want to be clear about that.

MR. SIMMS: I can perhaps explain a little bit what the reasoning of 4301 is. I don't know --

MS. AXELRAD: Did you write that one too?

[Laughter]

Do you want to stand up and introduce yourself for the record?

MR. SIMMS: My name is Steve Simms. I had the privilege to serve on the staff of the House Commerce Committee for sixteen years, and investigated, helped draft and then helped enact the Prescription Drug Marketing Act. I am a registered lobbyist for the trade association to which Mr. Shirley belongs, and that is one of the reasons why I have been silent until now, because I wanted the

Washington lobbyist to come, talk to you.

But, since your questions are not really about how the industry works but what is in the bill, it is kind of a little unfair to ask Mr. Shirley to try to explain in great detail why the bill was drafted that way.

MS. AXELRAD: I thought he was doing a good job.

[Laughter]

MR. SIMMS: Well, maybe I can help you a little bit.

MR. RAY: I think with the PDMA you have done enough.

[Laughter]

MR. SIMMS: Well, if I had to do it over again, I sure would have made a few changes, let me tell you. Okay? And, I apologize to my colleagues in the blood field too. I did the blood safety investigation for the committee too. So, I know a little bit about their plight. Okay?

At the time the bill was enacted, you know, we didn't have the licensing regime in place, nor had the agency implemented any of the PDMA regulations. Since that time you all have implemented these regulations. I refer specifically to 21 CFR 205.50 etc. In one subsection of that you already require distributors, as in other regulations on the books long-standing, you require manufacturers and retailers to keep very detailed records of

everything that is purchased and everything that is resold. Those records are available to the FDA inspectors, to the state people and specifically to law enforcement. So, the reason we felt that HR-4301 would serve the same purpose of maintaining the accountability of product at the wholesale level is because you already require the wholesalers to keep all these records of what they bought, when they bought it and who they sold it to. So, that is all in their business records. That is subject to audit by the FDA. And, it is all there. It is virtually the same thing as the pedigree.

MS. AXELRAD: But it isn't because the FDA inspector coming into the place would look at it and say, okay, now I know who you bought it from and who you sold it to, but they have to go criss-crossing the country to seven different people to go, find -- you couldn't do it that way.

MR. SIMMS: No, my point is that there is every incentive for the wholesaler not to falsify that information.

MS. AXELRAD: Just because they know somebody could come and look at it.

MR. SIMMS: Someone will come and look at it. Okay? They do in fact. And, that is why we felt that we no longer needed this rather burdensome and anti-competitive pedigree.

MS. AXELRAD: Well, why don't you get rid of

E(1)(a) entirely instead of just amending it the way you are suggesting be done --

MR. SIMMS: Well, we were trying to do as small a technical fix as we possibly could. Remember that we did not actually do away with the pedigree; we added another option. So, the way the bill was drafted, the pedigree would still apply to any product not first purchased through an authorized distributor. So, if some foreign product illegally entered into the country or, you know, some drug sample was repackaged or something, then that would be subject to the pedigree.

MS. AXELRAD: If it was first purchased from a manufacturer it would be subject to the pedigree the way it is written. If it went from a manufacturer to a secondary wholesaler and on from there, it would be subject to the pedigree because --

MR. SIMMS: Yes, with the definition of what an unauthorized distributor is. In the other part of the bill we tried to go back to what we thought was the original intent of the Congress and actually what your initial guidance was. I mean, we thought that if a manufacturer sold product to a licensed distributor we were not particularly worried about those products. All we tried to do in this section and, obviously, we didn't do it very well and I apologize for that, was to provide some small extra

safeguard for products that weren't manufactured in the United States and weren't sold into the system we were creating. It is a very simple concept that we created this system and then we were trying to protect it, and we added this extra little wrinkle to try to get the industry to police itself.

MS. AXELRAD: That is a sort of perfect segue into the next question that I wanted to ask because we were operating under one industry then, now we are going to be maybe operating under another whole scenario with the re-importation bill where drugs are going to be allowed to be re-imported from abroad that are not the actual approved product, and there will be a whole new stream of drugs introduced into the distribution system. Instead of having the pedigree that you thought was necessary to protect against abuses with that situation, now all they have to do is provide the certification. And, if you think it is hard to enforce and go check the chain for seven people or seven distributors in the United States, just imagine what it would be if you have to go hip-hopping around the world to try to figure out where it came from originally.

MR. SIMMS: Well, as I have read that language, and I read it a couple of weeks ago and I don't recall it perfectly, you would have to meet two requirements. Number one, you would have to have a pretty extensive paper trail,

which is a virtual equivalent of the pedigree, on products shipped abroad. You would also have to have statistically valid testing of each lot of the product. I mean, if any product could survive those two hurdles, I think it would be at least as safe as anything that was first sold through an authorized distributor in the United States. I mean, there are very, very high standards already in the language plus, it gives the FDA fairly carte blanche authority to add anything else they pretty much feel is needed.

MS. AXELRAD: Like a pedigree, in other words.

[Laughter]

MR. SIMMS: So, personally, I would be stunned if any significant volume of drugs came in --

MS. AXELRAD: Well, we don't really know.

MR. SIMMS: Yes. I did want to call one other thing to your attention. You were asking earlier about relying on people, and the committee expressly spoke on that subject in the House report, at page 17 --

MS. AXELRAD: Which House report?

MR. SIMMS: The House report on the Prescription Drug Marketing Act.

MS. AXELRAD: Can you just give for the record the year and the number --

MR. SIMMS: Yes, this is U.S. House of Representatives 100th Congress, first session, report number

100-76, from the Committee on Energy and Commerce, as it was then called.

MS. AXELRAD: And what year?

MR. SIMMS: This is in 1988.

MS. AXELRAD: Okay.

MR. SIMMS: It doesn't have a date on it. The way you actually reference it, it is report 100-76. It is the committee report.

MS. AXELRAD: No, I was just saying it could have been one for the '92 amendments.

MR. SIMMS: No.

MS. AXELRAD: I don't know how many House reports there may be on this. I am not trained in legislative history myself.

MR. SIMMS: No, there wasn't a big, formal report on the '92 amendments. On the bottom of page 17 it says the committee recognizes that wholesale pharmaceutical distribution system is based on contracts of sale whereby each party assumes, as well as relies upon, the good faith and veracity of the other party. The Uniform Commercial Code assumes such mutual good faith of the parties to facilitate all commercial transactions. In this connection, the Congress believes that the guarantee provision found in section 303(c) of the act, which is based upon the good faith of the buyer and seller is duly applicable to

wholesale distributors of prescription pharmaceuticals, etc.

So, basically, the committee was aware of that issue and I think the Uniform Commercial Code generally and the Food, Drug and Cosmetic Act generally -- you can ask your counsels -- does assume good faith, and there really is no other practical way to do it. But, this is from the report language and it goes on but I won't take any more of your time with that but it is there and you can look it up at your leisure.

MS. AXELRAD: Okay. Does anybody have any other questions?

MS. JACOBS: I have another question. Since Mr. Simms is here I wonder if he would want to make any comments on the blood-derived products part of the PDMA.

MR. SIMMS: We never intended to cover blood products in the first place, and I think it was only in the regulation that caused them to be covered under this act. As you recall the letter from Congressman Dingell, I think in 1994, there was no problem that we were aware or, or that I have been aware of since of counterfeiting of blood products or the kind of thing that we were trying to deal with in the prescription drug area. We thought that we had communicated well with the agency and that the blood community would be exempted from this, or at least regulated in a way that didn't cause any disruptions. So, I totally

support the proposals of the blood community to come to one of the solutions that they proposed for this, either exempting fractions or making them getting a wholesale license or, you know, whatever you all agree to. But, I mean, clearly the committee was not concerned about this and it is kind of funny in a way, although not funny to the blood industry now, with all the great minds that we had involved in this legislation, including then PMA who, incidentally, strongly opposed this legislation, which is --

MS. AXELRAD: Ironic.

MR. SIMMS: Ironic. But, anyway, no one even raised the issue of whether this covered blood and we had no concerns about counterfeiting of blood or whatever. There were other concerns about blood safety that you are well aware of, but not at all in the context of the PDMA or the kinds of things the PDMA regulated.

MS. STIFANO: And just to clarify, this included the fractionated products as well as the transfusion --

MR. SIMMS: Yes. We were not aware of any fraudulent re-importation or any sales out the back door by non-profit entities who are able to purchase at a specially reduced price, or any of the, you know, samples -- I don't know that there are any samples of these products. You know, none of the things that we were concerned about applied in the blood products, the blood fractions or any

other terms that the agency wants to apply to this industry. I didn't know that there are so many parts to it.

MS. O'ROURKE: Would you agree that the PDMA should apply to non-blood-related biological prescription drugs?

MS. STIFANO: In other words, the recombinant products, the gene therapy, some of the products coming from stem cells, use of stem cells?

MR. SIMMS: Well, the only response I can give you is what I recall about the committee's intent. I mean, my personal view I think is irrelevant on that particular question, I would submit, and virtually none of that existed back then and, if it did, we certainly weren't smart enough to know about it. So, I think the history and from what I recall from the committee's intent is totally silent on that. So, I am sure the agency will use its excellent judgment.

MR. SHIRLEY: I have one other thing because I don't think you are totally sold on the paper trail that I was talking about --

[Laughter]

MS. AXELRAD: We may or may not be sold. We are totally neutral here.

MR. SIMMS: Okay, from what I am understanding right now, especially from one of the comments you made that

you think it is wonderful that we are able at the end, down there, to pick up the thing and see who the very first one was. First of all, you are costing the consumers and the wholesalers millions of dollars in order to be able to do that. You can get the sam information within a 30 minute to an hour's time by telephone; we have fax machines; I can get you the information. Just because you want it in a convenient form there, at the very end, please weigh the cost basis on this. And, I know your hands are tied -- we have to have a pedigree unless we get the law changed on it, but the extra step in there is totally not necessary and, you know, I appreciate the opportunity to get to talk before you, especially since I wasn't on the schedule. So, thank you very much.

MS. AXELRAD: Thank you. There is somebody else I think who would like to speak, if you can do it fairly briefly.

MR. ROBERTSON: Good afternoon. My name is Derek Robertson, and I represent 15 hemophilia treatment centers, and I just wanted to talk to you briefly on the blood derivative question.

I was glad to hear that response earlier. It is certainly satisfying to hear that. I think one of the things that came out through the presentation of the blood centers and American Red Cross, which was touched on, is the

potential for increased costs. Clearly, hemophilia products are among the most expensive known. A hemophiliac, as many of you are aware, spends $100,000 a year on average just on clotting factor alone. So, typically, many hospitals and retail pharmacists do not keep an inventory of this product because it is very expensive to do that, and as the distribution channels have developed hemophilia treatment centers have been among those that supply small hospitals when needed with clotting factor. In some cases, the supply to these hospitals is even patient specific where a treatment center knows that a patient is going into the hospital for a particular procedure. The hospital says to the physician, well, okay, how much factor will we need for this procedure? Okay, you need 20,000 units. They will purchase those 20,000 units just for that procedure from the treatment center. The regs as written now would prevent a transaction like that from taking place.

What that means is not so much that the hospital could not get it from another source, because they probably could. They probably wouldn't get it from the manufacturer but they could probably get it from a wholesaler or from somebody else who has a wholesale distributor license. But, it is very likely that the cost would go up.

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When we talk about the pharmaceutical world where wholesalers will mark up, say, five percent or something

like that, that may sound reasonable. In the clotting factor business if, in the past you were paying 80 cents per unit from a manufacturer, like the American Red Cross for example, and now have to purchase that from a wholesaler with a five percent markup, that adds four cents per unit. If I purchase 15 million units, it is about $600,000. So, it is extremely significant when you are looking at the cost difference.

So, I think you want to really consider the comments that were just made in terms of the potential harm that is out there vis-a-vis the current distribution channels. Your first question asks what is the difference between, you know, specifically hemophilia products and others. One is definitely that typically patients do not get these products from their retail pharmacies. They will get it from a PBM or they will get it from a homecare company. And, the large percentage of the factor product is, in fact, through the homecare channels because that is the standard of care in home treatment so that people can become self-sufficient because in the treatment of hemophilia, you have to remember that patient care is primary and the foremost consideration, and immediate treatment of bleeds is critical. If you have a situation where, because of this act, the hospital has made a decision not to inventory product and can't get it quickly from a

hemophilia treatment center, then that can increase both morbidity and mortality. So, I think you have to be very careful in looking at that.

I really don't think there is an increased risk for adulteration, as was just mentioned. As a matter of fact, the risk will probably increase if you have this provision because now you will be dealing with people who do not typically deal with clotting factor. I wouldn't go so far as to say adulteration, but certainly outdated or short-dated product is much more likely to get into the marketplace if it is going through channels with persons who are not typically involved in the distribution of clotting factor and who don't fully understand all that goes into it.

So with that, I know I wasn't on the agenda but I just wanted to make those brief comments.

MS. AXELRAD: Thank you very much. Do you have any questions? No? Then, the last thing I was going to do is ask Mr. Young if he wanted to come up again, but I would just sort of say this is now optional since the two points I was going to cover were the issue of the certification and the issue of the impact of the re-importation bill on the secondary market. So, if you wanted to address those, that is what I was interested in hearing about.

MR. YOUNG: Let me comment briefly on the re-importation. I have read that language in its final

version. I think it provides the agency with the capacity to do about anything it wants with respect to the kinds of bells and whistles that are placed on re-imported drugs because I think the legislation did kind of bend over pretty far to try to assure that the drugs coming back into the U.S. are truly re-imported or U.S. approved NDA versions of the drug manufactured at approved facilities.

On the certification issue, it does go back to what Steve Simms said. It goes back to the reliance in our system on guarantees from those who supply. You know, that has been in there since the '38 act, and it has been the way regulated products under the Food and Drug Act move through commerce to the end user, and distributors and retailers use that guarantee form as a way to achieve whatever certainty they can from those who supply to them that the products meet certain standards, that they are not adulterated; they are not misbranded. That is in the guarantee form that is generally used here. So, those receiving drugs in the system rely on that guarantee to give them those assurances. Adding in that the drug was first purchased from an authorized distributor simply requires each person in the chain to assure that they have that guarantee from the person they bought it from, and someone down the road is putting that on the first time. So, it is just another way.

And, there is another commercial issue, and that

is that the PDMA discriminates, if you will, or puts a burden on unauthorized wholesalers to disclose who their sources are. Ms. O'Rourke is aware there was a code system at one time, and that code system was used by the industry substantially until they met with Ms. O'Rourke one day and she said no, no longer. In fact, they couldn't stop doing it fast enough, and they did stop doing it and that was after the amendments were passed in '92.

But disclosing, and what you heard from the fellow from Truxton earlier -- disclosing who you buy from is important commercial information. That is why, as I said earlier, down there, at that other level, those people down at the level distributing to doctors, to retail pharmacies, the ones who are not in the know about PDMA -- you will look a long time for a pedigree. You will look a long time for a doctor's office or a retail pharmacy that receives or asks for pedigrees, and there are a lot of small distributors out there who simply never got the word about this legislation. They may receive pedigrees, but I think down at that smaller level they don't deal in them, and it is not part of their commerce. At this level with R&S, Purity, Quality King and the other major wholesalers, they are very attuned to pedigree and they pass it on, and they use it when dealing with each other in that arbitrage system. Thank you.

MS. AXELRAD: Thank you. I think that concludes

our session for today. We have gotten a lot of useful information, too much really to absorb I think in one day. We will be looking for the comments. We hope you will submit them electronically. We check the docket for anything that comes in, in paper form. Things that are electronic we will be able to have access to. The comment period closes November 20th, and we will be working on what we want to tell Congress about what we intend to do with regard to the regulations and whether we think that there needs to be a legislative change.

Thank you to everybody who has participated in this. We are adjourned.

[Whereupon, at 3:50 p.m., the proceedings were adjourned]

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CERTIFICATE

I, **ALICE TOIGO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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